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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date:	December 12, 2011	
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Product:	Trade Name:	Endoscopic Monopolar Instruments and Accessories
	Common Name:	Electrosurgical Instruments and Accessories
	Classification Name:	Electrosurgical Cutting & Coagulation Device & Accessories

Predicate Device:

- K010192 - Endoscopic Tube Shaft Instruments for Monopolar Coagulation
- K033249 - Pajunk Modular Handle Instruments
- K970541 - Aesculap Modular Monopolar Electrodes
- K003717 - Tekno Medical Instruments for Laparoscopy

Device Description:

Endoscopic Monopolar Instruments and Accessories comprises three systems: Modular Three-Piece System, Modular Two-Piece System and Eco-Line. The respective components (handle, shaft and tip) of the Three-Piece and Two-Piece Systems can be used interchangeably, while Eco-Line consists of an assortment of insulated, single-piece instruments. All shafts and several modular handles are insulated and may be used with appropriate tip inserts to control bleeding in monopolar electrosurgical procedures. Additional insulated and non-insulated modular handles are intended for general manual (non-electrical) surgical use according to the design of the chosen tip.

Indications for Use:

Endoscopic Monopolar Instruments and Accessories are used in laparoscopic and other minimally invasive procedures for cutting, dissection, fixation and taking of biopsy samples, depending on the design of the tip. They are also intended to control bleeding by use of monopolar high-frequency electrical current.

Technological Characteristics

Bench testing was provided to characterize thermal spread and mechanical functions and robustness of the Endoscopic Monopolar Instruments and Accessories included in this submission. The device has similar technological and performance characteristics as the predicate device cleared under 510(k) K010192, as shown by the following summary:

Feature	Subject Device Endoscopic Monopolar Instruments and Accessories	Predicate Device Endoscopic Tube Shaft Instruments for Monopolar Coagulation
Indications for Use	Endoscopic Monopolar Instruments and Accessories are used in laparoscopic and other minimally invasive procedures for cutting, dissection, fixation and taking of biopsy samples, depending on the design of the tip. They are also intended to control bleeding by use of monopolar high-frequency electrical current.	These Endoscopic Tube Shaft Instruments are used in laparoscopic and other minimally invasive procedures for cutting, dissection, fixation and the taking of biopsy samples, depending on the design of the working tips. They are further intended to control bleeding by use of monopolar high-frequency electrical current.
Materials	Stainless steel, PPSU, Halar S	Stainless steel, PPSU, Halar S
	Nylon	Nylon insulation for an electrosurgical cutting and coagulation modular component has been cleared for marketing by K033249, Pajunk Modular Handle Instruments.
Sterility	Non-sterile	Non-sterile
Reusability	Reusable	Reusable
Sterilization Method	Steam	Steam
Electrical Safety	IEC 60601-1, IEC 60601-2-2 (2006)	IEC 60601-2-18
Design	o Two and Three-Piece Modular System	o Two and Three-Piece Modular System
	o Single-Piece Instruments	Single-Piece Instruments for electrosurgical cutting and coagulation have been cleared for marketing by K930666, Reusable Laparoscopic Instruments w/ Electrocautery

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Conclusion: The information provided in this 510(k) submission provides reasonable assurance that the subject device Endoscopic Monopolar Instruments and Accessories is safe and effective and that it is substantially equivalent to the predicate device with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 20 2011

Bema-GmbH & Co. Kg
% Business Support International
Ms. Angelika Scherp
Amstel 320-1
Amsterdam, Noord-Holland
Netherlands 1017AP

Re: K102921
Trade/Device Name: Endoscopic Monopolar Instruments and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 09, 2011
Received: December 13, 2011

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: ENDOSCOPIC MONOPOLAR INSTRUMENTS AND ACCESSORIES

Indications for Use:

Endoscopic Monopolar Instruments and Accessories are used in laparoscopic and other minimally invasive procedures for cutting, dissection, fixation and taking of biopsy samples, depending on the design of the tip. They are also intended to control bleeding by use of monopolar high-frequency electrical current.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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